

## REMARKS

Applicant respectfully requests reconsideration of the Office action dated August 25, 2004 in view of the foregoing amendments and the following remarks.

### *Claim 1 and its Dependent Claims*

Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Jacobsen et al. (U.S. Patent No. 5,833,632), March et al. (U.S. Patent No. 5,997,525), and Aldrich et al. (U.S. Patent No. 5,489,269); and under 35 U.S.C. § 102(e) as being anticipated by Paskar (U.S. Patent No. 6,623,449) and Goll (U.S. Patent No. 6,344,027). Claims 2-7, 9-18, and 33, which all depend directly or indirectly from claim 1, stand variously rejected under 35 U.S.C. § 102(b) and/or (e) based on the above five references. Claim 8 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over any of the above five references. As explained below, Applicant disagrees with the rejections but has nonetheless made certain claim amendments to clarify what Applicant regards as his invention.

Claim 1 as amended calls for a rigid end effector having a shape and including a rigid interior wall that defines a rigid fluid channel where the end effector is sufficiently rigid to maintain its shape during use. Applicant respectfully disagrees with Examiner's assertion that the term "rigid" is not limiting. Applicant submits that the term "rigid" is limiting in light of the comparison between "rigid" and "malleable" provided in page 12 of the specification. According to the specification, a "rigid" end effector may be made from a "suitable material" such as "stainless steel, titanium, composite structures of metal and plastic, and the like." In contrast, for a "malleable" end effector, "plastic materials

including polyurethane, high-density polyethylene, amorphous polyamide, polyetherimide, and polypropylene may be suitable.” Additionally, Applicant has amended claim 1 to further clarify the term of “rigid.”

Referring first to the Jacobsen patent, Jacobsen does not disclose, teach, or suggest a device having a rigid end effector that is sufficiently rigid to maintain its shape during use, as recited in amended claim 1. Instead, the only structure that may be considered an end effector is tubular guide wire 320 shown in Fig. 1. Tubular guide wire 320 includes “cuts, slots, gaps or openings” to “provide for lateral flexibility in the guide wire.” See col. 3, lines 14-21. The “lateral flexibility in the guide wire” allows “the shape of the guide wire to be controlled” during use by “chang[ing] the curvature of the tubular guide wire 320 as desired by the user.” See col. 3, lines 4-5 and col. 2, lines 56-57. Accordingly, Jacobsen does not disclose an end effector including a rigid interior wall that defines a rigid fluid channel where the end effector is sufficiently rigid to maintain its shape during use, as described and claimed in the present application.

Additionally, Jacobsen does not disclose, teach, or suggest an ejection mechanism adapted to eject the fluid with sufficient pressure to penetrate the organ, as called for in amended claim 1. Rather, as described at col. 4, lines 62-67 and col. 5, line 1, the Jacobsen device merely allows the medication “to leak from the bore of the guide wire into the vasculature passageway.”

Referring now to the March patent, March does not disclose, teach, or suggest a device having a rigid end effector that is sufficiently rigid to maintain its shape during use, as recited in amended claim 1. Rather, March discloses “an elongated, flexible

lasing transmission means.” See col. 2, lines 63-64. As shown in the various figures and described at col. 4, lines 31-36, the March patent discloses a catheter 10 made of flexible materials to “facilitate introduction of the distal end of catheter 10 into the patient’s left ventricle,” “generally through the femoral artery.”

Additionally, March does not disclose, teach, or suggest an ejection mechanism adapted to eject the fluid with sufficient pressure to penetrate the organ, as called for in amended claim 1. Rather, as described at col. 5, lines 21 to 25, March discloses a catheter that “is held in place for a suitable period of time, such as about 10 to about 300 seconds, allowing the agent to diffuse into the myocardium.” Further as described at col. 5, lines 49 to 50, March teaches another embodiment of the catheter that is configured such that the “agent will then seep out [of] the material at the distal portion of the catheter and permeate into the heart wall.”

Regarding the Aldrich patent, Aldrich does not disclose, teach, or suggest a rigid end effector that is sufficiently rigid to maintain its shape during use, as recited in amended claim 1. Rather, as shown in Figs. 1 and 5 and described at col. 4, lines 2-28, the Aldrich patent discloses a catheter 10 that includes “a flexible elongated member 11 and a lockable sleeve 26 positioned at the proximal end thereof, both formed from flexible plastic material tubes of different diameters.” Further, Aldrich’s flexible elongated tube member includes a distal portion 12 that may be configured into a “desired loop or pigtail configuration” during use. See col. 4, lines 5-6 and 65-66. Further, as described at col. 5, lines 8-19, the Aldrich patent teaches that the flexible tube member may be made from a “flexible plastic material” that can be “any thermoplastic

material such as polyvinyl chloride, polyamide including commercially available medical grade nylon, polypropylene, and polyethylene.”

Additionally, Aldrich does not disclose, teach, or suggest an ejection mechanism adapted to eject the fluid with sufficient pressure to penetrate the organ, as called for in amended claim 1. Rather, as described at col. 1, lines 11-13, the Aldrich device is used as a drainage catheter “introduced to a drainage site such as an abscess or a cavity in the biliary, nephrostomy, or urinary system.”

Referring now to the Paskar patent, Paskar does not disclose, teach, or suggest a device having a rigid end effector that is sufficiently rigid to maintain its shape during use, as recited in amended claim 1. Instead, as shown in various figures and described at col. 2, lines 36-41, Paskar discloses a catheter that “can be easily and simply reshaped into a variety of different shapes as desired by the user” and can “be reformed in the body to other desired shapes.” As described at col. 13, lines 32-37, Paskar’s catheter is a “curvable surgical element” that has a “curvable or deflectable distal tip.” Additionally, Paskar does not disclose, teach, or suggest an ejection mechanism adapted to eject the fluid with sufficient pressure to penetrate the organ, as called for in amended claim 1.

Referring now to the Goll patent, Goll does not disclose, teach, or suggest a device having a rigid end effector that is sufficiently rigid to maintain its shape during use, as recited in amended claim 1. Instead, as described at col. 4, lines 14-25, Goll discloses a device having an elongate shaft 14 with a flexibility “suitable for navigation from a remote access site to the treatment site within the human body” such as for “intravascular navigation to the coronary tissue from a remote access site in the femoral artery” or

“transthoracic navigation to the coronary tissue from a remote access point in the upper thorax.”

As discussed above, the cited references do not disclose, teach or suggest a device as claimed in amended claim 1. Claims 2-18 and 33 contain further limitations that distinguish the cited references. Accordingly, amended claim 1 and its dependent claims patentably distinguish the cited art, and Applicant respectfully requests that the rejections of claims 1-18 and 33 under 35 U.S.C. §§ 102 and 103 be withdrawn.

Applicant has added new claims 34-39, which depend from claim 1. Support for the new claims can be found throughout the specification as filed and no new matter is added. Applicant believes that claim 1 is now allowable. Therefore, new claims 34-39 are similarly allowable.

**Claim 19 and its Dependent Claims**

Claim 19 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Jacobsen et al. (U.S. Patent No. 5,833,632), March et al. (U.S. Patent No. 5,997,525), and Aldrich et al. (U.S. Patent No. 5,489,269); and under 35 U.S.C. § 102(e) as being anticipated by Paskar (U.S. Patent No. 6,623,449) and Goll (U.S. Patent No. 6,344,027). Claims 20-25, which all depend directly or indirectly from claim 19, stand variously rejected under 35 U.S.C. § 102(b) and/or (e) based on the above five references. Applicant disagrees with the rejections but has nonetheless made certain claim amendments to clarify what Applicant regards as his invention. For reasons similar to those stated above, Applicant respectfully submits that claims 19-25 patentably distinguish the cited references, and requests withdrawal of the rejections of those claims.

## CONCLUSION

Applicant believes that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, Applicant respectfully requests that the Examiner issue a Notice of Allowability covering the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

### CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on February 24, 2005.

  
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Suzanne Lukas-Werner

Respectfully submitted,

KOLISCH HARTWELL, P.C.

  
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Peter E. Heuser

Registration No. 27,902

Customer No. 23581

Of Attorneys for Applicant/Assignee

520 S.W. Yamhill Street, Suite 200

Portland, Oregon 97204

Telephone: (503) 224-6655

Facsimile: (503) 295-6679